DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 19 1999

0679 '99 MAR 22 A9:40

The Honorable Tom Harkin
United States Senate
Washington, D.C. 20510

Dear Senator Harkin:

Thank you for your letter February 1, 1999 cosigned by Senator Barbara A. Mikulski, regarding an abbreviated new drug application (ANDA) for a generic estradiol replacement therapy patch.

Please be assured that the Food and Drug Administration (FDA) rigorously reviews all chemistry, manufacturing, and controls data, as well as bioequivalence, labeling, and drug delivery data to assess the safety and efficacy of each ANDA before it is approved. This same review process will be applied before any ANDA for estradiol replacement therapy patch is approved.

Unfortunately, FDA cannot provide a more detailed response to your letter, because it is generally prohibited from disclosing information, not otherwise made public, about products that may be under review. Nor is FDA able to discuss the approval requirements for a drug product that is the subject of a pending Citizen Petition, as is estradiol. Comments on this Citizen Petition (#98P-0434) may be submitted in writing to the Dockets Management Branch at the address show below.

Food and Drug Administration
Dockets Management Branch
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

98P-0434

E
C 8 /ANS

We will submit your letter to the above-noted Docket.

Thank you for the opportunity to respond to your concerns relating to a generic estradiol replacement therapy patch. A similar letter has been sent to Senator Mikulski. If we may be of further assistance, please let us know.

Sincerely,

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: Dockets Management Branch

United States Senate

WASHINGTON, DC 20510

February 1, 1999

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

It has come to our attention that FDA has received an abbreviated new drug application for a generic estradiol replacement therapy patch. We applaud this development as an indication that the private sector is responding to the historic gap in research and resources devoted to women's health issues. However, some have reported concerns to us regarding the review criteria FDA will use to determine whether or not to approve a generic product, and we wish to relay to you, without prejudice, those concerns.

We believe the bio-equivalency standard FDA will use to assess a generic product is a reliable means of determining a drug's safety and efficacy. But some individuals have expressed the belief to us that a parallel assessment of the drug delivery mechanism developed for the generic product ought to be included in your review. We have been told that FDA ought to consider the potential impact of the delivery mechanism on the relative effectiveness and safety of the new treatment.

We hope this information is useful as you consider the most appropriate means of assessing this and other important new drugs. Thank you for your attention to this matter.

Sincerely,

Tom Harkin

Senator Tom Harkin

Barbara A. Mikulski

Senator Barbara Mikulski

TH/sc